



National Institutes of Health
Turning Discovery Into Health



Scientific Management Review Board

DRAFT REPORT ON STREAMLINING THE NIH GRANT REVIEW, AWARD, AND MANAGEMENT PROCESS

DRAFT

[MONTH] 2015

EXECUTIVE SUMMARY

[placeholder]

I. INTRODUCTION

A. Overview of NIH's grant-making process

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.¹

The National Institutes of Health (NIH) is a taxpayer-funded U.S. federal agency responsible for supporting basic, clinical, and translational biomedical research. NIH is comprised of 27 Institutes and Centers (ICs), each with its own mission, ranging from combatting cancer to curing vision disorders to addressing health disparities. Most of the research supported by NIH is conducted at universities and other public and private research institutions located in every state across the U.S., and NIH must ensure that the research it supports is scientifically meritorious and addresses basic, clinical, and translational research priorities. NIH primarily awards funds through a competitive awards process, in which scientists submit research grant applications that are reviewed by a panel of peers—other scientists who are knowledgeable about the science underlying the proposed research.

NIH grant applications typically undergo two levels of review. Upon receipt, applications are referred to both a scientific review group as well as one of 24 research-funding ICs for consideration. The selection of ICs is based on which IC is aligned most closely with the proposed research area. The Center for Scientific Review (CSR) at NIH manages the receipt and referral process and arranges the peer review of 73 percent of NIH grant applications; peer review of the remainder of the applications NIH receives is conducted by scientific review officers (SROs) within each IC.

In the first level of evaluation, peer review panels assign a score to each application based on scientific merit and other criteria.² Upon receiving a list of meritorious applications ranked by percentile score, the IC director and staff consider which applications will best advance their research mission and address program priorities. Because each IC has multiple priority research areas, and there are not enough funds to support all meritorious applications, ICs must be strategic in their selection of which applications to fund. Therefore, ICs are not required to adhere strictly to the ranking of scores assigned by peer review panels and can opt to fund a slightly lower-scoring application that addresses another priority research area. For example, ICs' missions typically encompass multiple diseases. ICs might want to support research portfolios in all of these disease areas even if all research applications for one disease receive better scores from peer review panels than any applications for another disease. These discussions occur during the second level of review, in which each IC's scientific advisory council/board makes recommendations regarding their concurrence with the primary review for each application as well as on the application's public health relevance and alignment with the IC's program priorities.³

¹ <http://www.nih.gov/about/mission.htm>

² http://grants.nih.gov/grants/peer_review_process.htm#Criteria

³ http://grants.nih.gov/grants/peer_review_process.htm#Second

1 This two-stage peer review process involves significant time and effort, but it promotes rigor and
2 fairness in the selection of meritorious research that will advance our understanding of diseases,
3 disabilities, other conditions, and human health. In its instructions to reviewers, NIH states that the core
4 values of peer review are expert assessment, transparency, impartiality, fairness, confidentiality,
5 integrity, and efficiency.⁴ The culture of peer review is at the heart of the NIH enterprise and academic
6 biomedical research, and it makes the biomedical research ecosystem stronger.⁵

8 NIH believes that peer review ensures that as much of the most meritorious and rewarding science as
9 possible, given budget constraints, gets funded. This is key to maintaining the competitiveness of
10 American biomedical research on the global stage. In an address to the National Academy of Sciences in
11 April 2013, President Obama noted that "to maintain our edge . . . we've got to protect our rigorous
12 peer review system and ensure that we only fund proposals that promise the biggest bang for taxpayer
13 dollars. . . that's what's going to maintain our standards of scientific excellence for years to come."⁶ In
14 December 2014, the Coalition to Promote Research, an alliance of universities, patient advocacy groups,
15 and professional societies wrote a letter to Congress in support of NIH peer review, saying "we stand
16 united in our support for the NIH, its mission, and its world-renowned peer review process."⁷ While
17 NIH's peer review process remains a key component of U.S. global leadership in biomedical research,
18 recent changes to the funding landscape have brought new challenges.

20 **B. Current landscape and challenges facing NIH's grant-making process**

22 NIH funding doubled between 1998 and 2003, increasing from \$13.7 billion to \$27.1 billion. However,
23 since 2003, NIH's purchasing power has declined substantially due to budget cuts and an increased rate
24 of inflation for medical research compared with other sectors.⁸ Thus, even a flat NIH budget has
25 resulted in a decline of overall purchasing power. The doubling of the NIH budget was followed by a
26 near doubling of the number of individual applicants, from approximately 19,000 in 1998 to about
27 32,000 in 2011.⁹ Similarly, the number of grant applications also doubled, from 31,000 in 1998 to more
28 than 62,000 in 2014.¹⁰ These increases in applicants and applications coincided with a leveling off of the
29 NIH budget and a net reduction in purchasing power.

31 What has caused this dramatic increase in applicants and applications? Trainees (including graduate
32 students and postdoctoral fellows) make up a large part of the biomedical workforce,¹¹ and increased
33 funding for biomedical research also led to an increase in the number of trainees. In concert with these
34 impacts of the budget doubling, demographic shifts in the Nation's population have also affected the
35 biomedical workforce. Scientists are remaining in the workforce longer and retiring later: in 1998, only
36 5% of NIH direct costs went to PIs over 65, whereas in 2014 this number rose to almost 12%.¹² Thus,
37 new investigators compete with prior generations of scientists for funding in an ever-expanding pool of
38 applicants.

⁴ <http://grants.nih.gov/grants/peerreview22713webv2.pdf>

⁵ <http://www.dispatch.com/content/stories/science/2014/12/14/1-nih-grant-process-boosts-science-through-peer-review.html>

⁶ http://grants.nih.gov/grants/peer_review_process.htm

⁷ <https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=15729>

⁸ Moses et al The Anatomy of Medical Research: US and International Comparisons. JAMA 2015.

<http://jama.jamanetwork.com/article.aspx?articleid=2089358>

⁹ <http://nexus.od.nih.gov/all/2012/08/09/more-applications-many-more-applicants/>

¹⁰ <http://report.nih.gov/NIHDataBook/Charts/Default.aspx?showm=Y&chartId=159&catId=2>

¹¹ http://report.nih.gov/investigators_and_trainees/acd_bwf/

¹² <http://nexus.od.nih.gov/all/2015/03/25/age-of-investigator/>

This trend shows no signs of abatement. The size of the biomedical research workforce continues to increase as trainees enter an ever-growing workforce with fewer faculty-level opportunities. The current job market for life sciences PhDs has suffered as a result. One recent analysis found that while 53%¹³ of life science graduate students want to become PIs, having their own labs, only 8% will become tenure-track faculty.¹⁴

For those who do become PIs, obtaining research funding is an increasingly challenging prospect. With many more applications and less available funding, NIH success rates (i.e., the percentage of reviewed grant applications that ultimately receive funding) have fallen from 25% on average in 1998 to 15% in 2014.¹⁵ The decline in success rate leads PIs to spend significantly more time preparing applications for grant funding. From 1998 to 2014, as the number of competing applications rose from 31,000 to 62,000,¹⁶ the number of grants awarded only rose from 10,000 to 12,500 (Figure 1).¹⁷

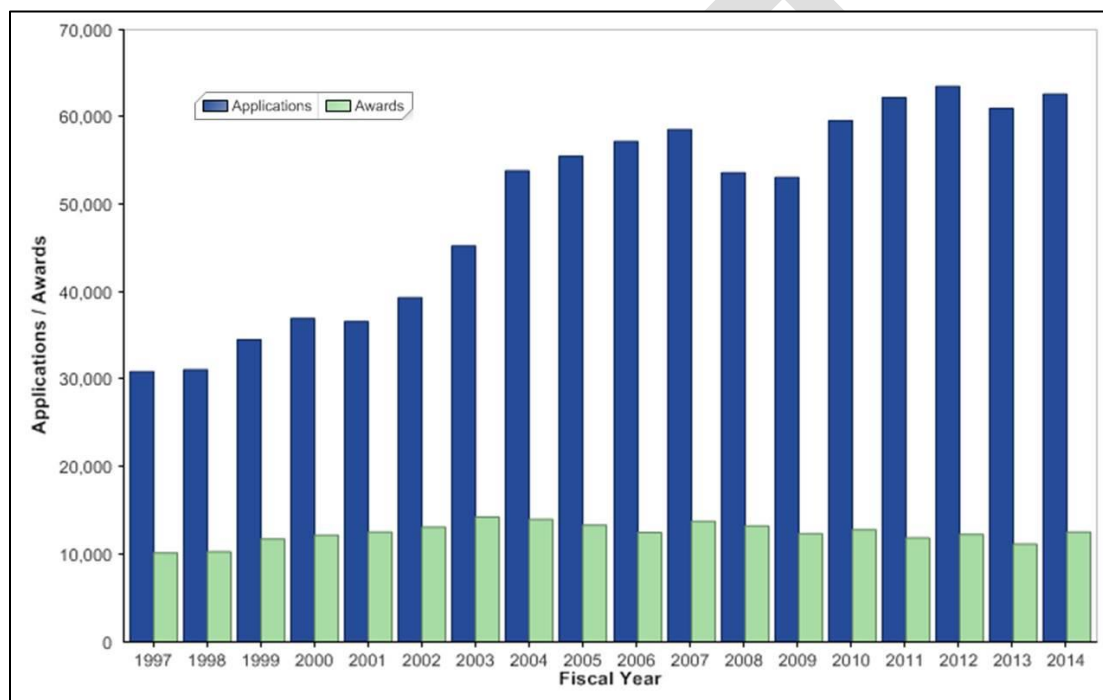


Figure 1. The number of applications submitted (dark blue bars) has risen markedly since 1997, while the number of awards (green bars) has remained relatively constant.

A recent article on the issue by several members of both NIH and the academic biomedical research community concluded that the funding system is “in perpetual disequilibrium, because it will inevitably generate an ever-increasing supply of scientists vying for a finite set of research resources and employment opportunities.”¹⁸ This disequilibrium has led to a vicious cycle, in which the hyper-

¹³ Sauermann H, Roach M. Science PhD career preferences: levels, changes, and advisor encouragement. *PLoS One*.2012;7(5):e36307. PMID: 22567149 and <http://ascb.org/where-will-a-biology-phd-take-you/>

¹⁴ <http://ascb.org/where-will-a-biology-phd-take-you/> and Biomedical Research Workforce Working Group, The Advisory Committee to the Director (2012). *Biomedical Research Workforce Working Group Report*. http://acd.od.nih.gov/Biomedical_research_wgreport.pdf

¹⁵ <http://report.nih.gov/NIHDatabook/Charts/Default.aspx?sid=0&index=0&catId=23&chartId=285>

¹⁶ <http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=200&catId=2>

¹⁷ <http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=159&catId=2>

¹⁸ <http://www.pnas.org/content/111/16/5773.full>

competitive environment further exacerbates the problem. PIs who do not receive funding continue to submit applications, and the number of investigators continues to increase. The increasing competition for funding also results in a drain on researchers' time. PIs spend more time preparing and submitting grant applications in order to fund their research. This creates a time sink that takes away from time that could be spent supervising their labs and providing valuable ideas and insight to their own research. In 2015, when NIH amended its submission policy to allow an unsuccessful resubmission to be submitted as a new application for the next grant cycle, the number of research applications reviewed by CSR has increased by more than 12% in each of the first two rounds. This will increase the burden on an already taxed review infrastructure and likely will decrease the success rate for research applications for 2015 despite a budget increase.

Another hurdle PIs face is the time lag between submission of their application and knowing whether their grant application will be funded. The average time from submission to award for an NIH grant is 9-10 months, with notable variance around this average. It is difficult for PIs to plan longer-term research projects or make purchasing or staffing decisions due to uncertainty about whether they will have the funds to support new acquisitions or payroll adjustments. The time delay for competing renewal applications may mean that research staff need to be laid off because there is insufficient funding for them to continue their work. In addition, numerous reporting requirements consume PIs' time and reduce their focus on research.

An additional burden on PIs, as well as NIH staff, is the high demand for review generated by the increase in the number of applications. Even as the number of applications has soared, the number of reviewers has remained relatively stable¹⁹. The sheer volume of applications has put a strain on the system, leading to an increased workload for reviewers that slows the process of evaluating applications. Today, reviewers often are asked to review more applications per cycle than in the past. When surveyed, reviewers indicated that eight is the maximum number of applications they are able to review, and they would prefer fewer (i.e., 4-6 applications)²⁰. However, some are being asked to review 12 or more applications per funding cycle. Staff from NIH's CSR have stated that the system is operating at capacity with the current volume.²¹

C. Charge to SMRB

The National Institutes of Health (NIH) Reform Act of 2006 (Public Law 109-482) established the Scientific Management Review Board (hereinafter the SMRB or the Board) to advise the NIH Director and other appropriate agency officials on the use of their organizational authorities.

The majority of NIH funding is distributed through grants to extramural researchers, so it is vital that NIH optimize grant-making in a way that streamlines the process while maintaining accountability and high performance standards. Given the challenges described above, NIH sought advice from the SMRB on ways to improve the grant-making process. The range of backgrounds and perspectives represented on the SMRB provided NIH with the opportunity to seek high-level advice regarding the grant-making process as a whole. Specifically, NIH asked members of the SMRB to recommend ways to further optimize the process of reviewing, awarding, and managing grants in a way that maximizes the time

¹⁹ <http://report.nih.gov/NIHDataBook/Charts/Default.aspx?showm=Y&chartId=285&catId=23>

²⁰ Roberts, L., Pearson, K., Amero, S. "Results of the Peer Review Capacity Evaluation". Presented to SMRB by OER, March 9, 2015

²¹ Richard Nakamura, Director of the NIH Center for Scientific Review, presentation to SMRB, December 15, 2014.

1 researchers can devote to research while still maintaining proper oversight. In addressing this charge,
2 the SMRB considered how NIH could:

- 3
- 4 • Streamline the grant-making process and shorten the time from application to allocation of
- 5 funds, and
- 6 • Address the administrative requirements on applicants and their institutions, scientific
- 7 reviewers, Council members, and NIH staff while maintaining a high-quality review and
- 8 management process.
- 9

10 SMRB members were asked to take the following steps in their deliberations:

- 11 • Assess each aspect of the current NIH grant-making process and determine whether any change
- 12 is warranted;
- 13 • Examine grant-making processes in other U.S. agencies, research funding bodies, and nations
- 14 and any available reviews of these systems in order to assess the strengths and weaknesses of
- 15 different approaches;
- 16 • Seek input from the general public, stakeholders in the biomedical research community,
- 17 participants in the grant-making process, and individuals with expertise in the review, awarding,
- 18 and management of biomedical research grants in the U.S. and abroad; and
- 19 • Identify possible strategies for improving the NIH grant-making process and articulate the
- 20 rationale for their selection.

21 **D. SMRB process**

22
23 SMRB members who formed the Working Group on NIH's Grant Review, Award, and Management
24 Process examined each step from writing applications to post-award oversight and looked for ways to
25 streamline the process. They met with experts and stakeholders in NIH's granting process, including
26 grant applicants and awardees, research administrators from institutions across the United States, NIH
27 Scientific Review Officers, the NIH Deputy Director for Extramural Research, and the Director of NIH's
28 Center for Scientific Review. They also heard from officials at other agencies and funding organizations
29 about different approaches to grant review and award processes. A full list of consultants can be found
30 in Appendix A. The Working Group provided updates to and solicited input from the entire SMRB during
31 its public deliberations on May 7, 2014; July 7, 2014; October 14, 2014; December 15, 2014; and July 6,
32 2015.

34 **II. PRINCIPLES FOR STREAMLINING NIH'S GRANT-MAKING PROCESS**

35
36 While the formal charge to the SMRB addressed streamlining the grant-making process, the Board
37 appreciates that NIH's grant review, award, and management process is complex, and that any
38 suggested changes likely will have ripple effects. As such, the Board kept a few principles at the
39 forefront when considering potential recommendations.

40
41 One primary principle during deliberations was that proposed changes should not compromise the
42 quality of peer review. Balancing speed of review with maintaining the high quality review that
43 investigators expect from NIH was of paramount importance to the SMRB.

1 The SMRB also was mindful of the follow-on effects of any recommendations. Decreasing the burden on
2 one group might increase burden in another area, for example, or speeding up one part of the process
3 could create a bottleneck at a future step. Similarly, the SMRB members gathered information about
4 potential unintended consequences that could result from changes in the process. The Board considered
5 all of these effects and potential effects carefully as they developed their recommendations to create
6 the maximum benefit with the fewest drawbacks.

8 As all possible consequences were weighed, the SMRB paid particularly close attention to any actions
9 that would increase the burden on investigators. Any potential solution that might streamline the grant-
10 making process but would require additional investigator burden was examined with extra scrutiny.
11 Unless a clear benefit that would outweigh the cost was identified, the SMRB did not consider these
12 actions further.

14 Finally, the SMRB intentionally avoided recommending changes that would disadvantage any
15 subpopulation of applicants. SMRB and NIH maintain that a diverse population of applicants and
16 grantees is critical to maintain a vibrant scientific and intellectual community.

18 **III. SMRB FINDINGS AND CONSIDERATION OF POSSIBLE CHANGES**

20 In accordance with their charge, the SMRB deliberated on potential changes to the grant award process
21 by examining each step of the process. For each step, the Board considered the challenges and
22 opportunities, as well as potential solutions, to streamlining the process. The following sections
23 describe the steps in NIH's grant review, award, and management process and some of the changes the
24 SMRB considered during their deliberations. Ultimately, not all of these potential changes were
25 recommended to NIH for their consideration. (The Recommendations section contains the potential
26 solutions endorsed by the SMRB).

28 **A. Writing and submission**

30 NIH grant applicants typically begin writing their applications several months prior to the due date,
31 investing significant time in articulating their project plans and goals. Once all parts of the application
32 are prepared, the applicant's institution or organization submits nearly all applications through the
33 Federal portal, Grants.gov. On average, each NIH extramural scientist submits 1.4 grant applications per
34 year.²² In a recent survey of nearly 1,800 NIH grant recipients, respondents estimated the time spent
35 preparing grant applications and subsequent progress reports as taking nearly 20 percent of their time²³.
36 This estimated time burden, combined with historically low success rates for grant applications, creates
37 a discouraging atmosphere among applicants and grantees who could be more productive if they spent
38 a greater portion of their time conducting innovative research.

40 Within this step, the Board considered the following potential strategies to streamline the process:

42 *A1. Improve the function of Grants.gov.*

²² <http://nexus.od.nih.gov/all/2012/08/09/more-applications-many-more-applicants/>

²³ Roberts, L., Pearson, K., Amero, S. "Results of the Peer Review Capacity Evaluation". Presented to SMRB by OER, March 9, 2015

1 Grants.gov serves as the Federal portal for submitting nearly all NIH grant applications. Established in
2 2003, it is operated under the governance of the Office of Management and Budget and managed by the
3 Department of Health and Human Services (HHS). Within HHS, the management of Grants.gov falls
4 under the purview of the Assistant Secretary for Financial Resources. NIH is one of 26 federal granting
5 agencies that use Grants.gov as their grant application portal. Though it works closely with the
6 Grants.gov Program Management Office, NIH has no direct control over the website's functionality.

7
8 In their deliberations, the SMRB noted problems with the Grants.gov application process. Applicants
9 find the system cumbersome and not compatible with software and databases used by most academic
10 and research institutions. The NIH Office of Extramural Research (OER) has been and will continue to
11 play an important role in working within the governance structure to overcome these difficulties to the
12 benefit of NIH applicants. The SMRB noted that OER's development and implementation of the
13 Application Submission System & Interface for Submission Tracking (ASSIST) represented a major
14 improvement in the grant submission process.²⁴ The Board was supportive of these ongoing efforts by
15 OER and did not make specific recommendations other than to endorse these efforts.

16
17 *A2. Implement a pre-application process.*
18

19 Many of the funding agencies and organizations engaged by the SMRB employ a pre-application process
20 in which potential applicants submit a brief summary of an application (a "pre-application") prior to
21 submitting the full application. The SMRB heard various scenarios in which these pre-applications are
22 reviewed and those applicants with ideas that are deemed most promising are invited to submit a full
23 application. The intent of such processes is to alleviate the burden on applicants who would otherwise
24 spend time writing a full application that is not likely to be funded and to alleviate the burden on
25 reviewers who would have fewer full applications to review.

26
27 The Board heard different approaches towards the review of these pre-applications. Some
28 organizations had program staff conduct the review themselves; others convened separate peer review
29 panels to review pre-applications and full applications; and still others convened the same panel of
30 experts twice, first to review the pre-applications and second to review the full applications.

31
32 NIH has employed a pre-application mechanism that, thus far, has been limited in scope. The Board
33 considered how a pre-application process could be applied to a broader range of applications, noting
34 the concern that voluntary submission of pre-applications and their review might lengthen the overall
35 time from initial contact with the NIH to award. However, such a process could enhance applicants'
36 success rates and thus decrease overall time to award if one considers obviating the need for
37 resubmission.

38
39 The SMRB found that the idea warranted further exploration and recommended that NIH consider
40 piloting this approach on a broader range of applications. Upon further consultation with CSR, the
41 Board endorsed an approach in which NIH could identify some upcoming Funding Opportunity
42 Announcements (FOAs) and include instructions for the submission of pre-applications. These pre-
43 applications would be reviewed by the same peer review panel that would review the subsequent
44 applications. Submission of pre-applications would be voluntary, and the results of pre-application
45 reviews might encourage or discourage applicants from submitting a full application, but would not

²⁴ <http://nexus.od.nih.gov/all/2015/04/30/more-assistance-options-for-submitting-your-application-to-nih/>

1 prevent them from doing so. Outcomes, such as number of full applications submitted and time to
2 award, would be compared to the results of similar FOAs released at approximately the same time.

3
4 Recommendation: NIH should pilot test an expanded pre-application
5 process in which potential applicants voluntarily submit brief
6 summaries of proposed projects. Those applicants with projects
7 deemed most promising will be encouraged to submit a full
8 application.
9

10 *A3. Fund investigators, not projects.*
11

12 The SMRB heard from NIH and other organizations about initiatives in which promising investigators
13 receive funding based on their overall research program rather than on specific projects. For example,
14 the Board discussed the Howard Hughes Medical Institute's Investigator and Early Career Scientist
15 programs, which support researchers engaging in high-risk, high-reward research and have admirable
16 track records for success. In addition to financial support, the programs minimize non-research
17 requirements to lessen the administrative burden on researchers.
18

19 Several NIH programs are experimenting with this model as well. The NIH Common Fund supports the
20 Pioneer Awards and New Innovator Awards, two programs for high-risk, high-reward research. Pioneer
21 Awards fund individual scientists of exceptional creativity, who propose pioneering – and possibly
22 transformative approaches – to major challenges in biomedical and behavioral research. New Innovator
23 awards support creative new investigators at an early stage of their career. Several NIH ICs also are
24 piloting person-centered grant mechanisms. For example, the National Institute of Environmental
25 Health Sciences initiated the Outstanding New Environmental Scientist (ONES) Program to foster the
26 careers of outstanding junior scientists while supporting innovative environmental health research.
27

28 The NIH also is piloting awarding longer grants to provide more stable support for investigators in order
29 to allow them more freedom to innovate and explore new lines of inquiry. This includes the National
30 Cancer Institute's Outstanding Investigator Award,²⁵ which will provide long-term support
31 to investigators who have extraordinary records of cancer research productivity and who propose to
32 conduct exceptional research, and the National Institute of General Medical Science's Maximizing
33 Investigators' Research Award (MIRA). By supporting an investigator's research through a single, unified
34 grant rather than through a series of separate, individual research project grants, MIRA will allow
35 researchers the freedom to explore new avenues of inquiry that arise during the course of their work.
36

37 The Board endorsed NIH's efforts in this area and urged the further development of similar programs.
38

39 *A4. Encourage grantee institutions to provide greater input to researchers preparing grant*
40 *applications.*
41

42 Many members of the Board as well as several invited speakers noted that research institutions have a
43 vested interest in improving the quality of applications submitted, even if it results in fewer submissions
44 to NIH. To ensure submission of the best possible applications, many institutions have developed
45 programs to help faculty prepare successful grants. For example, Vanderbilt University's Edge for

²⁵ <http://grants.nih.gov/grants/guide/pa-files/PA-14-267.html>

Scholars program²⁶ has several initiatives to help early career faculty navigate their careers. These activities include an institutional role in protecting time for grant preparation, spurring productivity, guidance in grantsmanship, facilitating community with other early career faculty through social media and other forums, and access to an extended network of senior scientists for advice and mentoring relationships. In particular, one initiative allows investigators to submit their grant application (original submission or a revision) for internal review by senior faculty members that have served on NIH review panels. A video of the review and a written critique are provided to the investigator. Similarly, Duke University has programs to help early career scientists with grant preparation by enlisting senior faculty with NIH review experience to provide detailed feedback on draft grant applications.²⁷

These are just two of many programs that exist at research institutions and professional societies across the country, all with the goal of helping early career scientists succeed in the NIH grant process. The SMRB discussed ways that these programs could become even more widespread, and they agreed that sharing best practices would be beneficial to the entire academic biomedical research community. However, the Board determined that this sharing and interaction would be best at the institutional level and that there was not a specific role for NIH in this area.

B. Receipt and referral

NIH's Division of Receipt and Referral in CSR receives approximately 84,000 applications per year, some of which are referred to other agencies. Applications for NIH funding that are compliant with NIH policies are assigned simultaneously to an NIH IC for funding consideration and to a Scientific Review Group (SRG) for peer review. On average, the receipt and referral process takes two weeks, and very few referrals are contested. Due to the speed and efficiency with which CSR accomplishes receipt and referral, the Board did not identify particular ways to streamline this step.

C. Peer review

As noted in the introduction, an application accepted by NIH for funding consideration undergoes a two-step review process. The initial step, peer review by a SRG or a Special Emphasis Panel consisting of recognized experts in relevant scientific fields, assesses the overall scientific merit of an application by scoring it based on pre-established criteria. Commonly used criteria include Significance, Approach, Innovation, Investigator, and Environment, though criteria may vary with different grant mechanisms.²⁸ The second level of review by the ICs' Advisory Councils takes other factors (e.g., public health, program priorities) into account in their funding recommendations. Although peer review is the gold standard for awarding grants for scientific research, the process is time-consuming and reviewers face a growing burden with an increase in the number of applications submitted to NIH. To try to address these challenges, the SMRB considered the following potential solutions:

C1. Increasing the Pool of Potential Reviewers

Given the challenges resulting from increased application volume, the SMRB deliberated on strategies for increasing the pool of potential reviewers. Data from internal analyses (NIH) indicate that many of

²⁶ <https://my.vanderbilt.edu/edgeforscholars/>

²⁷ <http://medschool.duke.edu/faculty/office-faculty-development/path-to-independence-program>
<http://medschool.duke.edu/faculty/office-faculty-development/k-club>

²⁸ https://grants.nih.gov/grants/peer/Review_Criteria_at_a_Glance_MasterOA.pdf

1 its grantees participate actively in the peer review process. However, a substantial number of
2 established investigators are not engaged in peer review for various reasons. Some investigators may
3 be hesitant to accept the invitation because they are already providing service to NIH in other capacities
4 or due to time constraints or other issues, and others may not have been asked. The Board discussed
5 several strategies for improving participation of NIH grantees, noting that NIH already encourages
6 investigators to participate in this process. For example, a recent NIH Guide Notice²⁹ addressed this
7 issue, and the SMRB strongly encourages NIH to convey such messages on an ongoing basis.

8
9 The Board also discussed broadening the range of grantees asked to serve as reviewers. Involvement of
10 senior, experienced investigators is vital to the quality and integrity of peer review. However, the Board
11 felt that less-established investigators also have a role in the peer review process, and at a time when
12 the biomedical research community increasingly is concerned about the next generation of researchers,
13 expanding the reviewer pool to include additional early career investigators could both alleviate burden
14 and directly help early stage investigators learn the process by participating in it. The use of additional
15 junior investigators would be balanced carefully with more senior researchers to ensure that breadth
16 and depth of expertise are represented on the review panel.

17
18 In addition to early stage investigators, the Board noted the importance of including more diversity in
19 the reviewer pool to reflect the growing diversity in the research workforce. In addition to those with
20 PhDs and medical degrees, the SMRB noted that NIH should consider extending review invitations to
21 those with a wider variety of degrees, such as those in dentistry, nursing, veterinary science, and public
22 health. This is in keeping with NIH efforts to broaden the definition of the biomedical workforce.³⁰

23
24 Recommendation: The pool of reviewers that NIH draws upon to
25 conduct its peer review should be deepened by continually
26 encouraging NIH grantees to participate in the process. In addition,
27 the pool of reviewers should reflect the diversity that NIH strives for
28 within the scientific workforce. Therefore, NIH should increase the
29 diversity of expertise called upon to participate in peer review and
30 should carefully integrate more early stage investigators in the
31 review process.

32 33 C2. Streamlining and Improving Upon Peer Review Meetings

34
35 The Board discussed numerous options for streamlining peer review meetings, such as increasing the
36 number of virtual meetings to reduce travel burden on reviewers and cost. The group affirmed the
37 value of in-person meetings, but also strongly encouraged exploration of virtual meeting options,
38 especially among established review groups where many of the participants have had in-person
39 meetings in the past. The SMRB noted that CSR and many ICs already have undertaken such innovations
40 and endorsed their efforts.

41
42 The Board also noted that the experience of participating in a peer review panel had changed over the
43 years. With new policies affecting things such as food and beverage provision, it is a less hospitable
44 experience than in the past. The provision of modest refreshments facilitates the discussion that forms

²⁹ <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-035.html>

³⁰ Biomedical Research Workforce Working Group, The Advisory Committee to the Director (2012). *Biomedical Research Workforce Working Group Report*. http://acd.od.nih.gov/Biomedical_research_wgreport.pdf

1 the core of rigorous peer review and maximizes the efficient use of reviewers' time and energy. The
2 Board urged rule makers to consider modest modifications to some of these policies to enhance
3 reviewer participation and satisfaction.

4 5 *C3. Modifying the Review Cycle* 6

7 Both primary peer review and secondary Advisory Council review occur in three cycles per year. The
8 current timing of the third cycle leaves NIH staff with little time to make grant awards for applications
9 reviewed in that cycle. Frequently, a backlog of applications from the two previous cycles has
10 accumulated by that time, creating an end-of-year workload that places a large burden on NIH staff.

11
12 To address this problem, the SMRB considered reducing the number of cycles per year from three to
13 two in an attempt to reduce burden for reviewers and NIH staff alike. However, the Board ultimately
14 decided that such a change was unlikely to affect the number of applications received, resulting in
15 greater burden for the two remaining cycles.

16 17 *C4. Implement a continuous submission policy for all grantees.* 18

19 The Board also discussed broadening the existing continuous receipt policy (rather than three deadlines
20 per year), similar to that of other agencies and organizations. Currently, NIH's continuous receipt policy
21 applies only to a limited pool of applicants (e.g., members of standing peer review committees and IC
22 Council members). The National Science Foundation (NSF) recently pilot tested a continuous submission
23 policy for one of its programs. Unexpectedly, this resulted in a substantial reduction in the overall
24 number of applications received. The SMRB considered whether this might be possible for NIH.
25 However, the organizations that the SMRB consulted handle a significantly lower volume of applications
26 than NIH, and the agencies operate their peer review systems differently. In addition, implementing a
27 rolling submission policy at NIH potentially could increase the time from application to award as the
28 period between submission and review may be extended. Even so, the SMRB felt that PIs and
29 institutions could benefit from expanding the continuous submission policy. Such an expansion would
30 enable all PIs to spread out their application efforts over time (if applying for multiple grants or
31 mechanisms). PIs also may benefit from eliminating the pressure of looming grant deadlines.
32 Continuous submission could alleviate burdens on research institutions as well by smoothing out
33 administrative workflow to prepare applications for submission. The Board also noted that because NIH
34 currently extends continuous submission privileges to those PIs that serve as reviewers, expanding this
35 policy to all grantees should not cause much disruption to the system.

36
37
38 Recommendation: NIH should consider pilot testing an expanded
39 continuous submission policy.
40

41 *C5. Strategically increase NIH review staff to handle large volume of applications.* 42

43 The SMRB noted that during this era of rapidly increasing numbers of applications, NIH review staff
44 maintained a relatively constant timeline for conducting peer review. However, sustaining this steady
45 flow has increased staff workload. With the rising number of applications unlikely to abate in the near
46 future, the staff burden may become untenable. The SMRB considered several strategies for increasing
47 review staff if a specific need is identified, such as allowing NIH intramural staff to rotate through CSR
48 and the other ICs to conduct peer review. However, training review staff is a long-term investment, and

1 temporary rotations may not be the best solution. The SMRB recommends that NIH consider increasing
2 review staff, but urges the agency to evaluate the need for additional staff carefully by first ensuring
3 that current staff have tools and procedures at their disposal to maximize efficiency.

4
5
6 Recommendation: NIH should ensure that review staff have the
7 necessary tools and procedures to maximize efficiency as well as
8 consider augmenting review staff to handle the increased volume of
9 grant applications when a specific need is identified.

11 12 **D. Award decision**

13
14 Following peer review, it falls to an IC Director to determine which applications to fund. The IC Director
15 carefully considers the peer review score in relation to the scores of other applications, the
16 recommendations of program staff and the Advisory Council, the needs and priorities of the IC, and, if
17 possible at the time, the IC's budget. The time taken to make funding decisions varies widely between
18 ICs, between funding mechanisms, and between fiscal years.

19
20 One reason that the timeframe varies is that it is difficult for IC Directors to make funding decisions
21 without knowing their exact budget for a fiscal year. While top-scoring grants often are funded and low-
22 scoring grants usually are not funded, the funding status of grants with mid-range scores remains
23 uncertain in the absence of a Congressionally-specified IC budget. In the last decade, the majority of
24 federal budgets have been appropriated during or after the 2nd quarter of the fiscal year. Delays in the
25 appropriations process for the new fiscal year can result in delayed funding decisions, as IC Directors
26 wish to avoid promising, and then revoking, funding.

27
28 The SMRB discussed a number of ideas to accelerate the award decision process. While the SMRB feels
29 that all of the recommendations put forward in this report are important, the three recommendations in
30 this section are most responsive to the charge and thus should be considered higher priority. As a
31 reflection of this, these recommendations are listed first in the summary table of recommendations in
32 Section IV of the report:

33 34 35 *D1. Fast-track awards for high priority applications.*

36
37 Most ICs currently fast-track high priority, top scoring applications that they are confident they will fund.
38 However, the percent of applications that are fast-tracked varies from one IC to another, and fast-
39 tracking is hindered in the absence of an agreed-upon federal budget. Thus, fast-tracking may be less
40 effective early in the fiscal year. In addition, when operating under a continuing resolution, ICs can
41 obligate only the amount of funds that they had obligated at the same time point the previous year.
42 Within these limitations, the SMRB supports fast-tracking the award of the maximum possible number
43 of high priority, top applications.

44
45 Recommendation: NIH should strive to fast-track awards for high
46 priority, top scoring applications to the greatest possible extent.

1 *D2. Sharing best practices for strategies to reduce time to award.*

2
3 Some of the practices that allow one IC to make decisions more quickly than another may be
4 transferable between ICs. However, differing IC missions and resources limit the portability of some
5 strategies for reducing decision time. The SMRB recommends that NIH ICs share best practices for
6 reducing the timeframe from submission of an application to awarding a grant.

7
8 In addition, to inform potential grantees of their application status as quickly as possible, as well as to
9 try to alleviate the end-of-year workload faced by grants management staff, the SMRB encourages IC
10 Directors to make funding decisions as early in the fiscal year as possible. The Board noted the wide
11 variance between ICs in the amount of time from application to award, and determined that efficiencies
12 and best practices should be shared among all levels of NIH leadership and staff.

13
14 Recommendation: NIH ICs should share best practices for reducing
15 time to award.

16
17 *D3. Provide partial funding of some grants while awaiting final NIH budget appropriations.*

18
19 In the absence of a final budget, ICs may be limited in the funds they can award at certain times of the
20 year (e.g., under a continuing resolution, described above). However, it may be possible to fund some
21 grants at a partial level initially in order to start awarding funds more quickly to a larger number of
22 grantees. The full amount of the award would be paid later in the year when the budget is finalized.
23 This might avoid PIs being forced to lay off and then re-hire staff while they await a funding decision,
24 even if the full amount of the grant is not made available until after the budget is determined.

25
26 The Board noted some caveats to this approach. Partial funding may be more viable for certain grant
27 mechanisms. For example, work on research project grants could begin with partial funding, whereas
28 large clinical trials, epidemiological studies, or training grants may require a full year's funding to launch.
29 Partial funding also could increase NIH administrative burden and slow down the process of issuing
30 funds because the partial and eventual full funding would have to be handled separately by NIH grants
31 management staff, potentially doubling the workload.

32
33 Despite these caveats, the SMRB found that instituting a partial funding process early in the fiscal year
34 could be of great benefit to investigators and research institutions and recommended that NIH devise
35 processes by which partial funding and subsequent full funding could be achieved with minimal
36 administrative burden.

37
38
39 Recommendation: In instances where such funding is practical, NIH
40 Institutes and Centers should provide partial funding early in the
41 fiscal year to promising applications to allow for the continuation or
42 initiation of a research program, with more complete funding to
43 follow when the IC budget for the fiscal year has been determined.
44 NIH should seek solutions to apply this two-step process with
45 minimal administrative burden.
46
47

1 While the SMRB feels that all of the recommendations put forward in this report are important, the
2 three recommendations in this section are most responsive to the charge and thus should be considered
3 higher priority. As a reflection of this, these recommendations are listed first in the summary table of
4 recommendations in Section IV of the report.

5 6 **E. Award issuance**

7
8 Applications that are to be awarded are reviewed for a variety of other considerations, including
9 verifying compliance with public policy requirements, disclosing other sources of support, confirming
10 animal or human subjects protocol approval, and assessing the management systems of the applicant
11 and their institution.³¹ In order to avoid time and energy spent providing administrative information
12 during the initial grant-writing process and to allow time for institutional approval processes to proceed
13 in parallel with peer review, this information is generally only requested for applications with favorable
14 scores. Collectively, these later-stage requests for information are known as “just-in-time procedures.”

15
16 While just-in-time procedures are designed to save applicants time during the process of grant writing
17 and submission, they can slow the issuance of awards. Taking time to gather documentation on human
18 subject approval, animal protocols, or biosafety approval, and the subsequent delivery and verification
19 of that information, increases the time it takes to issue an award. The SMRB noted that the just-in-time
20 process warrants further examination, and urged NIH to consider a more in-depth evaluation of these
21 procedures, potentially aided by outside efficiency experts.

22
23 ICs also may choose to negotiate changes to an applicant’s proposed budget before issuing a formal
24 Notice of Award. An IC can propose that an application’s timeline, scope, or aims be modified due to
25 programmatic changes, existing support for the same applicant, or peer reviewer concerns. In addition,
26 any budget change of 25 percent or more requires that the proposed project be explicitly altered to fit
27 the new budget. In response to such changes, applicants may modify their proposed research plan,
28 appeal an IC’s decision, or choose to withdraw their application.³² Once a final budget has been agreed
29 upon, a Notice of Award is issued to the applicant detailing the time and amount of funding for the
30 project. However, these last-minute budget negotiations can slow award issuance as the IC and the
31 applicant must agree before a Notice of Award can be issued.

32
33 Better software for grants management could streamline the process of budget negotiations between
34 applicants and ICs, as well as subsequent tracking of awards. NIH staff currently are working to develop
35 such systems to improve this process.

36
37
38 Recommendation: NIH should evaluate its just-in-time procedures to
39 identify potential mechanisms to enhance efficiencies including
40 modifying existing procedures.

41 42 **F. Award Management**

43
44 Individual applicants and institutions conduct and manage their research programs and are responsible
45 for the day-to-day operations of their grant. They are able to make some changes independently, such

³¹ http://grants.nih.gov/grants/managing_awards.htm#pre

³² <http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7fundgrant.aspx#b>

1 as no-cost extensions, carrying-over unobligated funds, and small-scale re-budgeting that does not
2 affect the project's scope. However, some grant actions explicitly require NIH approval: changes in key
3 personnel, the grantee's institution, or carry-over funds. In addition, NIH awarding offices monitor
4 grants through review of progress reports, correspondence with the grantee, audit reports, site visits,
5 and other information available to NIH.

7 PIs and institutions submit ongoing, required reports related to their project: financial reports, reports
8 of sub-awards to contractors, invention reports, progress reports, and the fulfillment of audit
9 requirements, as well as renewals of human subject or animal approval. Grants management specialists
10 review expenditure reports, keeping track of administrative and fiscal status. Program officers also
11 review progress reports in order to determine whether continued funding is merited. These reporting
12 requirements allow NIH to ensure that funds are spent in a productive manner and to evaluate whether
13 the grantee can complete the project within the allotted budget and timeframe.

15 Many grantees feel that this reporting places a high burden on the process of conducting research. A
16 2012 survey of more than 12,000 investigators with federally-funded grants³³ found that, on average,
17 faculty reported spending 42% of the time allocated to their research projects on administration
18 activities related to those projects, rather than actual research activities. Strikingly, this percentage has
19 remained the same since an initial survey of 6,000 participants in 2005. The same report listed proposal
20 preparation and post-award administration as top administrative burdens on researchers and found that
21 junior faculty reported larger burdens than their more senior colleagues. These administrative burdens
22 do not necessarily represent a single source, but rather the accumulation of burden across multiple
23 institutional and federal sources, including Institutional Animal Care and Use Committees (animal study
24 approvals), Institutional Review Boards (human subject approvals), biosafety panels, funding
25 organizations, and other potential science-regulating entities. These requirements are important to
26 protect humans and animals in research, the public's health and safety, and ensuring that tax dollars are
27 expended appropriately. Many of these reports and processes are mandated by Congress. However,
28 NIH recognizes the significant workload that these requirements produce and continually strives to
29 streamline the process as much as possible. The SMRB heard from OER about various ways they are
30 working to relieve administrative burden, and the Board encourages NIH to continue to pursue these
31 efforts.

33 *F1. Ongoing efforts to remove grant management burden*

35 NIH is committed to reducing burden on grantees. In Fall 2012, NIH implemented the Federal-wide
36 Research Performance Progress Report (RPPR) system to standardize and streamline the process of
37 submitting annual progress reports, which are read by program officers and grants management staff to
38 assess progress and compliance. As part of a larger White House initiative to reform reporting across
39 the federal government, NIH is taking steps to streamline effort reporting, make it easier to charge
40 reasonable costs to direct costs, and provide simple automatic no cost extensions under appropriate

³³ Not all respondents were NIH grantees; recipients of grants from any federal agency were included in the survey. According to the report, roughly 30 percent of respondents were in the biological and biomedical sciences, 30 percent were researchers in the physical sciences and engineering, 10-15 percent were from clinical and medical sciences, and just over 10 percent were in the social and behavioral sciences. The remainder included agricultural sciences, education, humanities and arts, and other non-listed fields.

Schneider, S. 2012 Faculty Workload Survey: Research Report. April 2012.

http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

1 conditions.³⁴ NIH also is simplifying the electronic submission of non-competing awards through an
2 online portal known as Electronic Streamlined Non-Competing Award Process, or eSNAP.

3
4 The multi-source nature of administrative burdens makes them particularly difficult to solve with
5 individual, targeted interventions, especially when reporting is mandated by statute. NIH currently
6 approaches the issue of administrative burden as an optimization problem, making changes throughout
7 the process so that various steps are more streamlined, automated, or otherwise user-friendly.

8 9 **G. Other opportunities to streamline the grant-making process**

10
11 In the course of its deliberations, the SMRB discussed potential strategies designed to streamline two or
12 more steps of the granting process.

13 14 *G1. Hire efficiency experts to review the granting process.*

15
16 Officials at other agencies and organizations reported that outside efficiency experts using a variety of
17 approaches, such as Lean Six Sigma principles, had helped them streamline their own granting and
18 decision-making processes. Some NIH practices cannot be changed due to statutory requirements, but
19 others may be modified in ways that alleviate burden on the extramural community as well as NIH staff.
20 To help NIH identify some of these policies and procedures subject to improvement, the Board
21 discussed the possibility of consulting outside efficiency experts. For example, these experts could work
22 with NIH to examine pre-application processes, identifying potential efficiencies by eliminating
23 redundancies in grant application requirements and forms. Experts also could evaluate the just-in-time
24 process to determine points where it could be less burdensome or altered to speed award issuance.
25 Another potential area where outside experts may be helpful is in procedures to monitor progress of
26 funded applications. Currently IC program officials and grant management specialists separately collect
27 information on ongoing awards. A fresh examination of this reported information, how it is collected,
28 and potential redundancies could result in new procedures that would reduce burden on grantees and
29 NIH staff.

30
31 Recommendation: NIH should consult outside efficiency experts to
32 review specifically targeted administrative aspects of the granting
33 process and identify potential efficiencies and improved policies and
34 procedures.

35 36 *G2. Consider using prize authority to solicit ideas for streamlining the process.*

37 NIH often taps the extramural research community for innovative ideas to tackle a range of challenges.
38 The SMRB considered recommending a prize competition to solicit solutions from the academic, private,
39 and philanthropic sectors that would streamline the grant award and/or management process. NIH has
40 the statutory authority to conduct prize competitions, wherein a small monetary award can be offered
41 in a public competition in exchange for a product or idea, allowing NIH to tap a larger community for
42 ideas and offer incentives for valuable contributions. The Board noted that the intricate, complex grant
43 award and management process is difficult to understand externally, possibly limiting successful
44 suggestions. However, a prize competition also could facilitate fresh perspectives on the bottlenecks in

³⁴ <http://nexus.od.nih.gov/all/2014/01/17/new-reforms-to-federal-grant-policies/>

1 the system. In an era of increasing popularity of crowdsourcing, the SMRB decided that this could be an
2 effective way to solicit new ideas to streamline the grant-making process.

3
4 Recommendation: Prize competitions should be considered as a
5 mechanism to generate innovative ideas to improve the grant
6 process.
7
8

9 *G3. Modifying NIH's budget and spending authority*

10
11 Each year, Congress appropriates funds for federal agencies to use in supporting their respective
12 missions. When conferring this authority to the agencies, Congress specifies criteria for spending these
13 funds, including stipulations that the funds be obligated within a particular timeframe. For NIH,
14 Congress appropriates funds on a yearly basis and instructs that funds must be obligated within a given
15 fiscal year. Unspent funds are returned to the U.S. Treasury. The stipulation to obligate funds by the
16 end of the fiscal year, combined with the frequent uncertainty of the budget for much of the year due to
17 continuing resolutions, creates substantial end-of-year workload for NIH staff and are major drivers of
18 the timeframe in which grants are awarded.

19
20 The SMRB discussed the potential of several alternative budget scenarios to hasten the award process.
21 Among these was the potential expansion of NIH's spending authority to two or more years. This would
22 allow award issuance beyond the end of the fiscal year and could result in a standard timeline from
23 application to award that would remain constant throughout the year.

24
25 The Board noted that the current appropriations system is not optimal for scientific research, which
26 often requires long-term projects and a mix of advance planning and flexibility to respond to urgent
27 scientific needs and opportunities. NIH planning and decision-making would benefit most from the
28 certainty conferred by multi-year budgets. Ideally, a five-year budget, coinciding with the length of
29 most NIH grants, would allow NIH the stability to engage in long-term planning while maintaining
30 requisite flexibility.

31
32 While the SMRB supports modification to NIH's budget and spending authority to be more conducive to
33 the pace and time horizon of scientific research, this decision is in the purview of Congressional
34 appropriators and not within the power of NIH to affect. The SMRB, however, encourages NIH to
35 convey the impact of delayed funding on advancing the nation's medical research priorities to motivate
36 decision-makers to consider solutions to achieve an expanded timeline for NIH spending authority.
37
38

39 **IV. RECOMMENDATIONS**

40
41 In order to better understand the NIH grant review, award, and management process and similar
42 processes in other agencies and organizations, the SMRB and the GRAMP Working Group sought input
43 from a range of individuals with expertise and experience from NIH, other U.S. federal agencies,
44 international governmental funding agencies, non-profit funders of biomedical research, and the
45 grantee community. With insights and input from these advisers as well as the depth of personal
46 experiences of Working Group members, the SMRB developed a series of recommendations for
47 streamlining NIH's grant review, award, and management process. The rationale for these

1 recommendations is discussed in the “SMRB Findings and Consideration of Possible Changes” section,
2 and they are summarized and listed below. While the SMRB feels that all of these recommendations are
3 important, the first three recommendations most directly address the charge and thus should be
4 considered higher priority. The remaining recommendations are presented in the order in which they
5 are discussed in the report.

DRAFT

1

Number	Recommendation	Page #
1	NIH should strive to fast-track awards for high priority, top scoring applications to the greatest possible extent.	13
2	NIH ICs should share best practices for reducing time to award.	13
3	In instances where such funding is practical, NIH Institutes and Centers should provide partial funding early in the fiscal year to promising applications to allow for the continuation or initiation of a research program, with more complete funding to follow when the IC budget for the fiscal year has been determined. NIH should seek solutions to apply this two-step process with minimal administrative burden.	14
4	NIH should pilot test an expanded pre-application process in which potential applicants voluntarily submit brief summaries of proposed projects. Those applicants with projects deemed most promising will be encouraged to submit a full application.	8
5	The pool of reviewers that NIH draws upon to conduct its peer review should be deepened by continually encouraging NIH grantees to participate in the process. In addition, the pool of reviewers should reflect the diversity that NIH strives for within the scientific workforce. Therefore, NIH should increase the diversity of expertise called upon to participate in peer review and should carefully integrate more early stage investigators in the review process.	11
6	NIH should consider pilot testing an expanded continuous submission policy.	12
7	NIH should ensure that review staff have the necessary tools and procedures to maximize efficiency as well as consider augmenting review staff to handle the increased volume of grant applications when a specific need is identified.	12
8	NIH should evaluate its just-in-time procedures to identify potential mechanisms to enhance efficiencies including modifying existing procedures.	15
9	NIH should consult outside efficiency experts to review specifically targeted administrative aspects of the granting process and identify potential efficiencies and improved policies and procedures.	17
10	Prize competitions should be considered as a mechanism to generate innovative ideas to improve the grant process.	17

2

3

4 V. CONCLUSIONS

5

6 [To be written following SMRB vote on findings and recommendations.]

7

8